



## NUCLEAR REGULATORY COMMISSION

[NRC-2021-0218]

### Information Collection: Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of submission to the Office of Management and Budget; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

**DATES:** Submit comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** David C. Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Obtaining Information and Submitting Comments

###### A. Obtaining Information

Please refer to Docket ID **NRC-2021-0218** when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2021-0218**.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov). The supporting statement and NRC Form 653, 653A, 653B are available in ADAMS under Accession Nos. ML22199A004 and ML22028A015.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov) or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

- **NRC's Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov).

#### B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by

selecting "Currently under Review - Open for Public Comments" or by using the search function.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## **II. Background**

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a *Federal Register* notice with a 60-day comment period on this information collection on April 4, 2022 (87 FR 19535).

1. *The title of the information collection:* "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."
2. *OMB approval number:* 3150-0001.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 653, 653A, 653B.

5. *How often the collection is required or requested:* There is a one-time submittal of information to receive a certificate of registration for a sealed source and/or device. Certificates of registration for sealed sources and/or devices can be amended at any time. In addition, licensee recordkeeping must be performed on an on-going basis, and reporting of transfer of byproduct material must be reported every calendar year, and in some cases, every calendar quarter.

6. *Who will be required or asked to respond:* All specific licensees who manufacture or initially transfer items containing byproduct material for sale or distribution to general licensees, or persons exempt from licensing, medical use product distributors to specific licensees, and those requesting a certificate of registration for a sealed source and/or device.

7. *The estimated number of annual responses:* 3,038 [2,285 reporting + 349 recordkeepers + 404 third-party recordkeepers].

8. *The estimated number of annual respondents:* 662 (156 NRC licenses, registration certificate holder + 506 Agreement States licensees and registration certificate holders).

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 109,510 (15,601 reporting + 1,122 recordkeeping + 92,787 third- party).

10. *Abstract:* Part 32 of title 10 of the *Code of Federal Regulations* (10 CFR), "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," establishes requirements for specific licenses for the introduction of byproduct material into products or materials and transfer of the products or materials to general licensees, or persons exempt from licensing, medical use product distributors to specific licensees, and those requesting a certificate of registration for a sealed source and/or device. It also prescribes requirements governing holders of the specific licenses. Some of the requirements are for information which must be submitted in an application for a certificate of registration for a sealed source and/or device, records

which must be kept, reports which must be submitted, and information which must be forwarded to general licensees and persons exempt from licensing. As mentioned, 10 CFR part 32 also prescribes requirements for the issuance of certificates of registration (concerning radiation safety information about a product) to manufacturers or initial transferors of sealed sources and devices. Submission or retention of the information is mandatory for persons subject to the 10 CFR part 32 requirements. The information is used by the NRC to make licensing and other regulatory determinations concerning the use of radioactive byproduct material in products and devices.

Dated: November 21, 2022.

For the Nuclear Regulatory Commission.

David C. Cullison,  
NRC Clearance Officer,  
Office of the Chief Information Officer.

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